In the

United States Court of Appeals

For the Seventh Circuit

No. 03-4292

XECHEM, INC., AND XECHEM INTERNATIONAL, INC.,

Plaintiffs-Appellants,

v.

BRISTOL-MYERS SQUIBB COMPANY,

Defendant-Appellee.

Appeal from the United States District Court for
the Northern District of Illinois, Eastern Division.
No. 03 C 1920—**Amy J. St. Eve**, *Judge.*

ARGUED JUNE 8, 2004—DECIDED JUNE 23, 2004

Before EASTERBROOK, KANNE, and DIANE P. WOOD, *Circuit Judges.*

EASTERBROOK, *Circuit Judge.* The Hatch-Waxman amendments to the Food and Drug Act entitle pharmaceutical companies that first bring a drug to market to a five-year period of exclusivity, even if the drug is unpatented. 21 U.S.C. §355. Bristol-Myers Squibb was first to market with paclitaxel, a compound derived from the bark of the yew tree and useful in combating some cancers. Bristol-Myers calls its formulation Taxol®, which has been a commercial success. The exclusivity period was due to

expire in July 1997, and many other drug producers geared up to sell generic paclitaxel once the market opened.

In order to sell paclitaxel, a new producer must file (and win administrative approval of) an abbreviated new drug application or ANDA. Another provision of the Hatch-Waxman legislation affects the processing of such applications. It creates what has come to be called the Orange Book, in which drug manufacturers list their products and any patents that they believe apply. If the manufacturer of a drug claims patent protection, then the Food and Drug Administration will not approve an ANDA unless the applicant certifies that it believes the patent to be invalid or not infringed by the generic compound. If the applicant so certifies, then the FDA will proceed unless the original maker files a patent-infringement suit within 45 days. Such a filing defers approval for 30 months, or until the litigation has been resolved, whichever is earlier.

Shortly before its exclusivity was to end, Bristol-Myers listed in the Orange Book two patents covering the administration of paclitaxel. It sued all firms that filed ANDAs for that drug, so the 30-month deferral took effect. Courts ultimately determined that all important claims of both patents are invalid. See *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (holding eight claims invalid and remanding for further proceedings concerning two others; Bristol-Myers dismissed its suit rather than put those to the test). Just before the 30-month deferral was to expire, Bristol-Myers listed a *third* patent in the Orange Book. This reset the 30-month clock, which continued to run until January 17, 2002, when Bristol-Myers withdrew this listing after the third patent, too, had been declared invalid. Obtaining multiple deferrals has been criticized by the Federal Trade Commission, which wants Congress to amend the statute so that a maximum of one is available. The FTC observed that Taxol is one of eight drugs covered by sequential 30-month deferrals as a result

of delayed patent listings in the Orange Book—and that *every* patent listed for any of these eight had been declared invalid or not infringed. *Generic Drug Entry Prior to Patent Expiration* 48-56 (2002) (the report's reference to "every" patent is limited to those on which litigation had been concluded by the time the report was published).

Xechem is a maker of generic drugs. It makes and sells paclitaxel throughout the world—but not in the United States, where it has never filed the ANDA necessary to obtain approval. It began this antitrust suit in 2003, contending that the maneuvers we have described, and a few others besides, excluded rivals and exposed consumers to elevated prices. The district court dismissed the complaint under Fed. R. Civ. P. 12(b)(6), see 274 F. Supp. 2d 939 (N.D. Ill. 2003), concluding that the suit is untimely—that the four years allowed by 15 U.S.C. §15b began in 1997, when Xechem did not file an ANDA, and thus expired before this litigation started.

Rule 12(b)(6) authorizes the dismissal of a complaint that fails to state a claim on which relief may be granted. Exclusionary patent-related practices that violate the antitrust laws are valid claims. See *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965); *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261 (7th Cir. 1984). The complaint alleges that paclitaxel lacks good substitutes and that Bristol-Myers extended its market power through underhanded means, injuring both consumers and rival producers. These assertions may be right or wrong, but how could the complaint be dismissed under Rule 12(b)(6)? The district court found, not a defect in the *claim*, but the presence of an affirmative defense. See Fed. R. Civ. P. 8(c). Orders under Rule 12(b)(6) are not appropriate responses to the invocation of defenses, for plaintiffs need not anticipate and attempt to plead around all potential defenses. Complaints need not contain *any*

information about defenses and may not be dismissed for that omission. See, e.g., *Gomez v. Toledo,* 446 U.S. 635 (1980); *United States v. Northern Trust Co.*, No. 04-1148 (7th Cir. June 22, 2004); *United States Gypsum Co. v. Indiana Gas Co.*, 350 F.3d 623 (7th Cir. 2003).

Only when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6). See *Walker v. Thompson*, 288 F.3d 1005 (7th Cir. 2002). Bristol-Myers believes that this is such a case, because the 69-page complaint (have Xechem's lawyers never read Fed. R. Civ. P. 8(a) and (e)(1)?) states, among many other things, that Bristol- Myers' stratagems led Xechem in 1997 to place "on permanent hold" the process of filing its own ANDA for paclitaxel. That decision started the clock, Bristol-Myers insists, and more than four years elapsed before Xechem filed suit. Xechem tendered an amended complaint asserting that the 1997 decision was not "permanent" but was subject to reevaluation once the Hatch-Waxman delay ended. The district court deemed this change irrelevant and refused on that ground to allow the amendment. 2003 U.S. Dist. LEXIS 21430 (N.D. Ill. Nov. 26, 2003).

The difference between "never" and "maybe later" could be important. Fiddling with the complaint's language is unnecessary, though. "On hold" itself implies the possibility of change. It is not as if Xechem had abandoned generic drugs, sold its operating assets, and turned itself into a mutual fund. The complaint alleges that it makes and sells many drugs, including paclitaxel, and that it has obtained both U.S and foreign patents for aspects of that line of business. What sense would there have been in making an irrevocable decision, when changes in Bristol-Myers' conduct (and the decisions of other drug makers) could affect the future profitability of selling generic paclitaxel in the United States? The phrase "on permanent hold" reads more

like a lawyer's flubbed attempt to say that events in 1997 led to a definitive decision not to file at that time, than like a report of a business decision *never* to sell paclitaxel in the United States, come what may.

On this understanding—an appropriate one, given the rule that, when acting on the pleadings, courts must indulge the readings and make the assumptions that favor the plaintiff, see *Hishon v. King & Spalding*, 467 U.S. 69 (1984)—the case cannot be dismissed under Rule 12(b)(6). The period of limitations for antitrust litigation runs from the most recent injury caused by the defendants' activities rather than from the violation's inception. See, e.g., *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321 (1971); *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586 (1957). Cf. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 188-91 (1997) (describing how this approach works). The complaint alleges that Bristol-Myers committed new exclusionary acts (for example, listing the third patent in the Orange Book and thus obtaining a second 30-month postponement of generic competition) within the four-year period preceding the complaint, and that these new acts extended the period during which Bristol-Myers held a monopoly, causing additional antitrust injury. This suffices under established principles. See, e.g., *United States Gypsum*, 350 F.3d at 628; *Brunswick*, 752 F.2d at 271-72. That it may be too late to complain in 2003 about what Bristol-Myers did in 1997 does not imply that it is too late to complain about what it did in 2000 or 2002; improperly prolonging a monopoly is as much an offense against the Sherman Act as is wrongfully acquiring market power in the first place. Each discrete act with fresh adverse consequences starts its own period of limitations. Cf. *National Railroad Passenger Corp. v. Morgan*, 536 U.S. 101 (2002).

Bristol-Myers asks us to affirm on an alternative ground: that Xechem cannot establish damages, because its injury is too uncertain or remote. See *Associated General*

Contractors of California, Inc. v. California State Council of Carpenters, 459 U.S. 519 (1983); *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982). Certainly Xechem faces a difficult task; it cannot recover damages unless it can show that (and when) it would have entered the market in the absence of anticompetitive practices, and how much money it would have made. That Xechem *still* has not filed an ANDA for paclitaxel, even though Bristol-Myers has not listed a patent for Taxol in the Orange Book since 2002, is a hurdle that it must vault to establish injury. But a prediction that the plaintiff will be unable to meet its challenges is not a good reason to dismiss a complaint under Rule 12(b)(6). If Bristol-Myers should make and support a motion for summary judgment under Fed. R. Civ. P. 56, then the district court could conduct the necessary analysis on an evidentiary record.

REVERSED AND REMANDED

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit